

SEBOBALANCE SPOT CONTROL - salicylic acid gel

Laboratoire Dr. Renaud

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

ACTIVE INGREDIENT

Salicylic Acid 1% w/w.

INACTIVE INGREDIENTS

WATER/EAU • ALCOHOL DENAT • SORBITOL • METHYL GLUCETH 20 • GLYCOLIC ACID • GLYCERIN • ALPHA-GLUCAN OLIGOSACCHARIDE • SODIUM CITRATE • BUTYLENE GLYCOL • PROPYLENE GLYCOL • SODIUM HYDROXIDE • AMYLOPECTIN • XANTHAN GUM • DEXTRIN • HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT • ARGININE • CELLULOSE GUM • ALLANTOIN • PEUMUS BOLDUS LEAF EXTRACT • ASCOPHYLLUM NODOSUM EXTRACT • ANTHEMIS NOBILIS FLOWER EXTRACT • CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT • CENTAUREA CYANUS FLOWER EXTRACT • TILIA VULGARIS FLOWER EXTRACT • CALENDULA OFFICINALIS FLOWER EXTRACT • HYPERICUM PERFORATUM EXTRACT • ASPARAGOPSIS ARMATA EXTRACT • ETHYLHEXYLGLYCERIN • PHENOXYETHANOL •

For the treatment of acne. Dries and clears acne pimples, blackheads and whiteheads and allows skin to heal.

DIRECTIONS

Morning and evening, after a thorough cleansing of the skin, apply SeboBalance Spot Control Gel locally on cutaneous imperfections. Then apply the usual day or night cream. Renew application 1 to 3 times daily.

WARNINGS

For external use only. Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. Avoid direct contact with the eyes. If product gets into the eyes, rinse liberally with water. Discontinue use if skin irritation develops or increases. If irritation persists, consult a doctor. This product contains alpha-hydroxy-acids (AHA) which may increase sensitivity to the sun and lead to skin burn. Reduce sun exposure and use a sunblock during the use of this product and the week following its use.

Image of carton label



Gel local
anti-boutons
SeboBalance
Spot
Control Gel

8 ml / 0.27 FL.OZ.



Laboratoire
Dr Renaud

INGRÉDIENT MÉDICINAL :

Acide salicylique à 1 % p/p.

ACTIVE INGREDIENT:

Salicylic Acid 1% w/w.

**INGRÉDIENTS INACTIFS /
INACTIVE INGREDIENTS:**

WATER/EAU •
ALCOHOL DENAT. •
SORBITOL •
METHYL GLUCETH 20 •
GLYCOLIC ACID •
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ALPHA-GLUCAN OLIGOSACCHARIDE •
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BUTYLENE GLYCOL •
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AMYLOPECTIN •
XANTHAN GUM •
DEXTRIN •
HAMAMELIS VIRGINIANA
(WITCH HAZEL) EXTRACT •
ARGININE •
CELLULOSE GUM •
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HYPERICUM PERFORATUM EXTRACT •
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ETHYLHEXYLGLYCERIN •
PHENOXYETHANOL •

Assèche et aide à faire disparaître les boutons d'acné et facilite la guérison de la peau.

MODE D'EMPLOI : Matin et soir, sur une peau parfaitement nettoyée, appliquer le Gel local anti-boutons SeboBalance localement sur les imperfections cutanées. Appliquer ensuite la crème de jour ou la crème de nuit habituelle. Renouveler l'application locale 1 à 3 fois par jour.

MISES EN GARDE : Pour usage externe seulement. L'emploi topique d'autres produits anti-acné utilisés simultanément ou appliqués immédiatement après l'usage de ce produit peut augmenter le dessèchement ou l'irritation de la peau. Dans ce cas, un seul produit devrait être employé, sauf indication contraire d'un praticien de soins de santé. Éviter tout contact avec les yeux; le cas échéant, rincer abondamment avec de l'eau. Cesser l'emploi si une irritation excessive de la peau apparaît ou si l'irritation s'aggrave. Si l'irritation persiste, consulter un praticien de soins de santé. Ce produit contient des acides alpha-hydroxylés (AHA) qui peuvent augmenter la sensibilité au soleil et entraîner une brûlure de la peau. Réduire l'exposition au soleil et utiliser un écran solaire pendant l'utilisation du produit et pour la semaine suivant son utilisation.

Dries and clears acne pimples, blackheads and whiteheads and allows skin to heal.

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Image of bottle label



Gel local
anti-boutons
SeboBalance
Spot Control
Gel

8 ml / 0.27 FL. OZ.



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Assèche et aide à faire disparaître les boutons d'acné et facilite la guérison de la peau. MODE D'EMPLOI :
Matin et soir, sur une peau parfaitement nettoyée, appliquer le Gel local anti-boutons SeboBalance localement sur les imperfections cutanées. Appliquer ensuite la crème de jour ou la crème de nuit habituelle. Renouveler l'application locale 1 à 3 fois par jour. **MISES EN GARDE :** Pour usage externe seulement. Éviter tout contact avec les yeux; le cas échéant, rincer abondamment avec de l'eau. Cesser l'emploi si une irritation excessive de la peau apparaît ou si l'irritation s'aggrave. Si l'irritation persiste, consulter un praticien de soins de santé. Ce produit contient des acides alpha-hydroxylés (AHA) qui peuvent augmenter la sensibilité au soleil et entraîner une brûlure de la peau. Réduire l'exposition au soleil et utiliser un écran solaire en tout temps. **For the treatment of acne. Dries and clears acne pimples, blackheads and whiteheads and allows skin to heal. DIRECTIONS:** Morning and evening, after a thorough cleansing of the skin, apply SeboBalance Spot Control Gel locally on cutaneous imperfections. Then apply the usual day or night cream. Renew application 1 to 3 times daily. **WARNINGS:** For external use only. Avoid direct contact with the eyes. If product gets into the eyes, rinse liberally with water. Discontinue use if skin irritation develops or increases. If irritation persists, consult a doctor. This product contains alpha-hydroxy-acids (AHA) which may increase sensitivity to the sun and lead to skin burn. Reduce sun exposure and use a sunblock at all times. **INGREDIENT MEDICINAL :** Acide salicylique à 1% p/p. **ACTIVE INGREDIENT:** Salicylic Acid 1% w/w. **INGRÉDIENTS INACTIFS / INACTIVE INGREDIENTS:** WATER/EAU • ALCOHOL DENAT. • SORBITOL • METHYL GLUCETH 20 • GLYCOLIC ACID • GLYCERIN • ALPHA-GLUCAN OLIGOSACCHARIDE • SODIUM CITRATE • BUTYLENE GLYCOL • PROPYLENE GLYCOL • SODIUM HYDROXIDE • AMYLOPECTIN • XANTHAN GUM • DEXTRIN • HAMAMELIS VIRGINIANA (WITCH HAZEL) EXTRACT • ARGININE • CELLULOSE GUM • ALLANTOIN • PNEUMUS BOLDUS LEAF EXTRACT • ASCOPHYLLUM NODOSUM EXTRACT • ANTHEMIS NOBILIS FLOWER EXTRACT • CHAMOMILLA RECUTITA (MATICARIA) FLOWER EXTRACT • CENTAUREA CYANUS FLOWER EXTRACT • TILIA VULGARIS FLOWER EXTRACT • CALENDULA OFFICINALIS FLOWER EXTRACT • HYPERICUM PERFORATUM EXTRACT • ASPARAGOPSIS ARMATA EXTRACT • ETHYLHEXYLGLYCERIN • PHENOXYETHANOL •

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U.S. Dist.: RENAUD SKIN CARE LABORATORIES Plattsburgh, N.Y. 12901



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Keep out of reach of children.

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SEBOBALANCE SPOT CONTROL

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62499-384
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
AMYLOPECTIN (UNII: 4XO4QFV777)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
ARGININE (UNII: 94ZLA3W45F)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ALLANTOIN (UNII: 344S277G0Z)	
PEUMUS BOLDUS LEAF (UNII: Q4EWM09M3O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
CHAMOMILE (UNII: FGL3685T2X)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
ASPARAGOPSIS ARMATA (UNII: 2936KN6IIG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62499-384-11	1 in 1 CARTON		
1	NDC:62499-384-07	8 g in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/30/2010	

Labeler - Laboratoire Dr. Renaud (202501565)

Registrant - Laboratoire Dr. Renaud (202501565)

Revised: 6/2010

Laboratoire Dr. Renaud